

Application No. 10/607,752  
Attorney Docket: 11000.1042c3  
Response to Office Action mailed November 4, 2005

### **REMARKS**

Favorable consideration of the subject patent application is respectfully requested in view of the above amendments and the following remarks.

Withdrawn claims 3-5 have been cancelled from the application. Method claims 17, 22 and 23 have been amended to remove reference to claims 26 and 27. In addition, claim 22 has been amended to remove reference to the treatment of cancer. Claim 28 has been amended to replace the term "A fusion protein" with the term "The fusion protein". Newly added claims 29-31 are drawn to subject matter previously rejected in claims 17, 22 and 23, namely methods employing the compositions of claims 26 and 27. Applicant specifically reserves the right to rejoin the method claims once the product claims have been determined to be allowable.

It is urged that support for all the above amendments may be found throughout the specification as originally filed and that none of the amendments constitute new matter. It is further submitted that the amendments are not being made for reasons of patentability and therefore do not give rise to prosecution history estoppel.

### **Claim Rejection under the Doctrine of Double Patenting**

Claims 14, 24, 25, 26 and 28 stand rejected under doctrine of obviousness type double patenting as being unpatentable over claims 1, 5, 7, 24 and 25 of US Patent 6,436,898. While Applicant does not acquiesce in this rejection, a Terminal Disclaimer of the subject application over US Patent 6,436,898 is submitted herewith in order to expedite allowance of the claims.

It is respectfully submitted that this rejection may thus be properly withdrawn.

### **Claim Rejection under 35 USC §112, second paragraph**

Claim 28 stands rejected under 35 USC §112, second paragraph, as being indefinite. Specifically, the Examiner has objected to the use of the term "A fusion protein encoded by the polynucleotide". As noted above, the term "A fusion protein" has been amended to read "The fusion protein".

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It is urged that one of skill in the art, on being provided with the instant specification, would be able to clearly determine the metes and bounds of all the presently pending claims and that this rejection of claim 28 may be properly withdrawn.

**Claim Rejection under 35 USC §112, first paragraph**

Claims 25-27 and 28 stand rejected under 35 USC §112, first paragraph, as lacking an adequate written description. Specifically, the Examiner has objected to the recitation of sequences having at least 95% identity to SEQ ID NO: 116. Applicant believes that this rejection should not have been applied to claim 28, and that this is a typographical error. Applicant respectfully traverses the rejection of claims 25-27.

Independent claim 25 is drawn to fusion proteins comprising an amino acid sequence having at least 95% identity to SEQ ID NO: 116, wherein the fusion protein possesses at least one of the following properties: (a) an ability to stimulate proliferation of T cells from individuals exposed to *Mycobacterium tuberculosis*; and (b) an ability to stimulate interferon-gamma secretion from T cells from individuals exposed to *Mycobacterium tuberculosis*. Claims 26 and 27 are drawn to compositions comprising such fusion proteins. The fusion proteins of claim 25 possess at least one functional property that is common to fusion proteins comprising SEQ ID NO: 116, namely the ability to stimulate proliferation of, or interferon-gamma secretion from, T cells from individuals exposed to *Mycobacterium tuberculosis*.

Applicant notes that, in the Responses to Specific Comments on the Guidelines for Examination of Patent Applications under 35 USC §112, first paragraph, "Written Description Requirement" (Federal Register Vol. 66, No. 4, January 5, 2001), it is clearly stated that "[d]escribing the complete chemical structure, i.e., the DNA sequence of a claimed DNA is one method of satisfying the written description requirement but it is not the only method". The Response continues to state "[t]herefore, there is no basis for a *per se* rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed". Applicant also notes that the Guidelines themselves state "The written description requirement for a claimed genus may be satisfied ... by disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or

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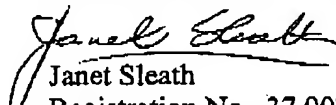
chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure or by a combination of such identifying characteristics". The Guidelines also state that "[d]isclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient".

It is urged that the fusion proteins recited in claim 25 possess sufficient common identifying characteristics to fusion proteins comprising SEQ ID NO: 116, namely specific percentages of sequence identity and clearly recited functional characteristics, to clearly distinguish the claimed fusion proteins from other materials and that these identifying characteristics would indeed lead one of skill in the art to conclude that the applicant was in possession of the claimed fusion proteins at the time the application was filed. Applicant thus submits that the rejection of claims 25-27 under 35 USC §112, first paragraph, as lacking an adequate written description, may be properly withdrawn.

#### Conclusion

Favorable reconsideration and allowance of the amended claims is respectfully requested. Should the Examiner have any further concerns regarding the subject application, she is respectfully requested to telephone the undersigned at 206.382.1191.

Respectfully submitted,

  
Janet Sleath  
Registration No. 37,007

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SPECKMAN LAW GROUP PLLC  
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